

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

**IN RE: DIGITEK PRODUCT LIABILITY  
LITIGATION**

**MDL NO. 1968**

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**THIS DOCUMENT RELATES TO ALL CASES**

**DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF THE  
MOTION TO DISMISS COUNT 5 OF THE MASTER CONSOLIDATED  
COMPLAINT FOR INDIVIDUALS**

**I. INTRODUCTION**

Plaintiffs, in their Brief Opposing Defendants' Motion to Dismiss Count 5 of the Master Consolidated Complaint for Individuals, concede that they can claim no private right of action under the Federal Food, Drug and Cosmetics Act ("FDCA"). Instead, Plaintiffs attempt to recast Count 5 of their Master Complaint as stating that the FDCA merely sets the standard of care for Plaintiffs' negligence *per se* claim. Without further explanation, Plaintiffs cite cases noting that the FDCA has set the standard of care in a negligence *per se* claim and allege that they are simply doing the same. Plaintiffs' arguments fail, and Defendants are entitled to the dismissal of Count 5 because (1) controlling law establishes that such FDA-based negligence *per se* claims are improper, and (2) Plaintiffs' negligence *per se* claim is, no matter how described, an attempt to assert a private cause of action under the FDCA, which is expressly prohibited. *See* 21 U.S.C. § 337(a).

## II. LAW AND ARGUMENT

### A. This Court Should Follow the Majority of Cases That Dismiss FDCA-Based Negligence *Per Se* Claims as a Matter of Law.

The parties agree that the FDCA does not allow for private individuals to enforce, or prevent violations of, the FDCA. *See* 21 U.S.C. § 337(a). Plaintiffs, however, argue that they can use the FDCA to bring a private cause of action so long as the Act merely establishes the standard of care under state tort law. (*See* Resp. in Opp’n 2.) As authority for this proposition, Plaintiffs cite several cases that have allowed the FDCA to establish the standard of care under state tort law. (*See* Resp. in Opp’n 2.) Although there are a handful of courts that have allowed plaintiffs to enforce the FDCA through state tort law, the majority of cases prohibit this type of back-door enforcement. *See Vanderwerf v. SmithKline Beecham Corp.*, 414 F. Supp. 2d 1023, 1028, n.2 (D. Kan. 2006) (listing cases that did not allow the FDCA to establish the standard of care for negligence *per se* claims). Moreover, Plaintiffs’ cases have limited precedential value. *See* James M. Beck and John A. Valentine, *Challenging the Viability of FDCA-Based Causes of Action in the Tort Context: The Orthopedic Bone Screw Experience*, 55 Food & Drug L.J. 389 (2000) (explaining why cases cited by Plaintiffs are inapposite) For example, *Orthopedic Equipment Co. v. Eutsler*, the only Fourth Circuit case cited by Plaintiffs, was decided in 1960 and did not address Congressional intent or Section 337(a) of the FDCA. *See Orthopedic Equipment Co. v. Eutsler*, 276 F.2d 455 (4th Cir. 1960).

This Court should follow the majority of cases that recognize the impropriety of allowing the FDCA to set the standard of care in a negligence *per se* claim. The reasoning of the *Talley* Court is instructive in recognizing that the negligence *per se* doctrine “substitutes a general legislative judgment for a specific judicial judgment in instances where the legislature has set forth the standard of conduct that a ‘reasonable man’ must follow.” *Talley v. Danek Medical, Inc.*, 179 F.3d 154, 158 (4th Cir. 1999). The *Talley* Court cautioned that the negligence *per se*

doctrine is “cabined” so that it does not become a “mechanism to enforce any statute through a private right of action...” by (1) not allowing all statutory provisions to establish a standard of care, and (2) even when a statutory provision does specify a standard of care, requiring that the plaintiffs are nonetheless still required to prove the remaining elements of a negligence claim. *Id.* at 159. Statutes such as the FDCA that protect the public at large, rather than an individual or class of persons, cannot be used to establish a standard of care in a negligence *per se* claim. The *Talley* Court correctly cites Section 286 of the Restatement (Second) of Torts to define a negligence *per se* action (*id.* at 158), but the “corollary of § 286,” Section 288, provides “the conditions under which the courts will not adopt the legislative or administrative standard of conduct as that of a reasonable man for the purposes of a negligence action.” *See* Restatement (Second) of Torts § 288, Comment a. (1965). Section 288 states that “[t]he court will not adopt as the standard of conduct of a reasonable man the requirements of a legislative enactment or an administrative regulation whose purpose is found to be exclusively (a) to protect the interests of the state....” *Id.* Comment b. to Section 288 gives further insight into the type of legislation that should not establish the standard of care for a negligence *per se* claim, explaining:

Many legislative enactments and regulations are intended only for the protection of the interests of the community as such, or of the public at large, rather than for the protection of any individual or class of persons. Such provisions create an obligation only to the state, or to some subdivision of the state, such as a municipal corporation. The standard of conduct required by such legislation or regulation will therefore not be adopted by the court as the standard of a reasonable man in a negligence action brought by the individual.

*Id.* at Comment b. In other words, statutes whose purpose is to protect the public interest in general do not set the standard of care for an individual plaintiff’s negligence *per se* claim.

The FDCA’s “overriding purpose [is] to protect the public health.” *United States v. An Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 798, 89 S.Ct. 1410, 1418 (1969). In construing

the very provisions Defendants are alleged to have violated, the Court in *Gourdine v. Crews* held that “[t]hese statutes and regulations...are framed to protect the public in general.” *Gourdine v. Crews*, 405 Md. 722, 757, 955 A.2d 769, 790 (2008); *see also Sandoz Pharmaceuticals Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 230 (3d Cir. 1990) (holding that the FDCA “requires the FDA to protect the public interest...”). For this reason, Congress left no doubt of its intention that “all such proceedings for the enforcement, or to restrain violations, of [the FDCA] shall be by and in the name of the United States” – not individual plaintiffs. 21 U.S.C. § 337(a); *see Mylan Laboratories, Inc. v. Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993); *see also Wagner v. Anzon, Inc.*, 453 Pa. Super. 619, 630, 684 A.2d 570, 575 (Pa. Super. Ct. 1996) (holding that “[t]here is a close relationship between whether a statute provides a private cause of action and whether it protects an individual harm that would support application of the negligence *per se* doctrine.”). This Court should not allow Plaintiffs to use a statute meant to protect the public health at large as the basis for an individual state claim of negligence *per se*.

**B. Plaintiffs’ Negligence *Per Se* Claim is a Private Cause of Action for Alleged Violations of the FDCA that is Expressly Prohibited by 21 U.S.C. § 337(a).**

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Plaintiffs’ negligence *per se* claim thwarts the intent of Congress by recasting a private cause of action for violations of the FDCA as a negligence *per se* claim. The District Court in *Talley* recognized that “[t]o allow a state *negligence per se* action based upon alleged violations of the FDCA would defeat the purpose of [§ 337(a)].” *See Talley*, 7 F. Supp. 2d at 731, n.4. The *Mylan* Court likewise held that allowing a plaintiff to bring a Lanham Act claim based on alleged violations of the FDCA “would, in effect, permit Mylan to use the Lanham Act as a vehicle by which to enforce the Food, Drug and Cosmetic Act...and the regulations promulgated thereunder.” *Mylan*, 7 F.3d at 1139.

Plaintiffs' artful pleading is an attempt to allege violations of the FDCA through their negligence *per se* claim. Plaintiffs assert that they "have made it clear that they are invoking the Defendants' violation of the FDCA to prove the Defendants' liability for separate underlying torts by establishing the standard of care and not, as Defendants suggest, to form a private cause of action." (Resp. in Opp'n 3.) But the Master Complaint tells a different story. Count 5 alleges a series of violations of the FDCA and merely concludes that "[t]he acts and omissions set forth above, demonstrate that Defendants failed to meet the standard of care set by the applicable statutes and regulations...." (Master Compl., ¶ 95.) Plaintiffs' claim for negligence *per se* presents exactly what the *Talley* and *Mylan* Courts warned against, and this Court should dismiss Count 5 as an apparent attempt by Plaintiffs to bring a private cause of action for alleged violations of the FDCA.

### III. CONCLUSION

Plaintiffs' Count V: Negligence *Per Se* should be dismissed as a matter of law because the FDCA is a general statute intended to promote the public health – not to create private enforcement actions through negligence *per se* claims.

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**CERTIFICATE OF SERVICE**

I, Rebecca A. Betts, counsel for Defendants hereby certify that on June 2, 2009, I electronically filed the foregoing "Defendants' Reply Memorandum in Support of the Motion to Dismiss Count 5 of the Master Consolidated Complaint for Individuals" with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.



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